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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/196,867 11/20/98 KELSALL

B 14014.0312

EXAMINER

HM22/1023

DECLoux, A

MARY L MILLER

NEEDLE & ROSENBERG
SUITE 1200 THE CANDLER BULDG
127 PEACHTREE STREET N E
ATLANTA GA 30303-1811

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

10/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/196,867

Applicant(s)
Kelsall et al

Examiner
DeCloux, Amy

Art Unit
1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8-14-01 and 10-01-01
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment and declaration, filed 8-14-01 and 10-01-0, respectively, (Paper Nos. 24 and 25, respectively) are acknowledged and have been entered. Claims 1-8 and 10 are pending and presently under consideration.

2. The rejections of record can be found in the previous Office Action mailed 3-7-01 (Paper No. 21). In view of applicant's amendment and declaration, filed 8-14-01 and 10-01-01, the outstanding rejections have been withdrawn. However, in view of Applicant's amended claims, a new grounds of rejection has been applied to the instant claims. It is also noted that no supplemental IDS has yet been received by the office, though applicant indicated in said amendment that a supplemental IDS would be submitted along with the executed declaration.

3. In Applicant's amendment, filed 8-14-01, the instant claims 1-8 and 10 were amended to recite the negative limitation that the ligand of this invention "is not an antibody having the myelomonocytic recruitment inhibitory activity of monoclonal antibody 5C6". For support for this amendment, Applicants point to page 22, lines 27-28, where it states that "Balb/C mice were given intraperitoneal injections of either CR3 antibodies (1 mg of clone M1/70 or 0.5 mg of 5C6, both of which are non-opsonizing antibodies (8, 32)." However it is pointed out that the record does not set forth a clear nexus between "non-opsonizing" activity as recited in the instant specification, and not having "myelomonocytic recruitment inhibitory activity" as now recited in the instant claims. Furthermore, even if there is a nexus, it is not clear from the record that these two activities encompass embodiments of identical scope.

Applicants further contend that further support for this amendment to the claims can be found in references 8, 11 and 13 as cited on pages 2 and 23-24 of the instant specification where the examiner notes they are referred to by number only, and also as listed with titles in the reference section on page 27 of the instant specification. Applicants further contend that all the references cited in the instant application are incorporated in their entireties by reference as stated on page 25 of the instant specification and are part of the specification as if they were fully set out therein. However the examiner points out that to incorporate material by reference, the host document / application must identify with detailed particularity what specific material it incorporates and clearly indicate where the material is found in the various documents. See Advanced Display Systems, Inc. v. Kent State Univ., 54 USPQ2d 1673 (Fed. Cir. 2000) citing In re Seversky, 177 USPQ 144, 146 (CCPa 1973). This is further supported by Ex parte Raible (8 USPQ2d) where the appellant's specification did not specifically refer to the Bently reference, and the BPAI agreed with the examiner that the general incorporation by reference in the specification of the application under examination is

insufficient to support specific claim limitations. Therefore, the negative limitation to the instant claims, is not supported by the instant application.

Furthermore, applicant has urged that *Amtel Corp. Vs. Information Storage Devices, Inc.* 53 USPQ2d 1225 supports the position that recitation of a reference title in the specification provides a description of matter inserted into the claims. However, the fact situation in *Amtel* does not correspond to that instantly. In *Amtel*, the title was discussed in the body of the specification in relationship to the citing of a reference which showed art known features which were taught as being capable of being incorporated into the disclosed invention. Instantly, however, the title is merely cited in a bibliography, and there was nothing in the body of the disclosure to indicate that applicant was directing one to negate embodiments involving an antibody having the myelomonocytic recruitment activity of the monoclonal antibody 5C6. Applicant has thus improperly inserted new matter by way of a negative limitation, *In re Graselli*, 218 USPQ 769.

NEW GROUND OF REJECTION

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-8 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-8 and 10 are not supported by the specification or by the claims as originally filed. There is no support in the specification or claims as originally filed for the recitation "wherein the ligand is not an antibody having the myelomonocytic recruitment inhibiting activity of monoclonal antibody 5C6". There is no written description of the claimed invention in the specification or claims as originally filed. Thus the claimed invention constitutes **new matter**.

6. No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37

CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. Or a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
October 22, 2001

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182/1644